FEB 10 2014

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# 510(k) SUMMARY

K131146

510(k) owner's name:
ACI Medical, LLC
1857 Diamond St.
San Marcos, CA 92078
Tel. 760 744 4400
Fax 760 744 4401
Contact name: Ed Arkans
Prepared: February 7, 2014

- Trade name – ArtAssist
- Common name – Compressible limb sleeve or Pneumatic compression device
- Classification name – Compressible limb sleeve (21 CFR 870.5800, Product Code JOW)

The legally marketed devices to which our firm is claiming equivalence is the ArtAssist device (K942530).

**Device description**

The ArtAssist device is a pneumatic compression device that applies pressures to the limbs in timed sequences. There is a pump controller that contains a housing, an air pump, an air reservoir, electrical power supply, pressure regulation, timing regulation and safety circuitry. A set of limb cuffs contains air bladders that fill and apply pressure. A tubing set delivers the air from the pump controller to the limb cuffs.

The ArtAssist device increases blood flow to the limb. This is achieved by applying rapid compression to the soft tissues of the limb. The ArtAssist device empties the veins and reduces venous pressure. The reduced venous pressure results in an increased driving pressure to greatly improve blood flow.

**Intended use of the device**

Specific indications include:
When surgery is contraindicated
While waiting for surgery
Intermittent claudication
Rest pain
Diabetic foot
Ischemic neuritis
Arterial ulcers
Gangrene
Poor runoff

**Summary of the technological characteristics**

The device has the same technological characteristics as the predicate device except that it has been modified to include changes in the control mechanism from mechanical pressure regulation to electronic type and from discrete electronics to microcontroller based.

**Performance data**

Pressure/timing graphs obtained in the laboratory demonstrate substantial equivalence to the predicate device. The device has been tested to safety requirements (UL 60601-1) and EMC requirements (IEC 60601-1-2)

**Conclusions drawn from testing**

The laboratory test results demonstrate that the device performs as well as the predicate device since it applies equivalent pressures and timing and is therefore as effective as the predicate device. The risk analysis, safety and EMC tests performed demonstrate the device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 10, 2014

ACI Medical, LLC
c/o Mr. Ed Arkans
1857 Diamond St.
San Marcos, CA 92078

Re: K131146
Trade Name: ArtAssist
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: December 24, 2013
Received: December 27, 2013

Dear Mr. Arkans:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Indications for Use Statement

Device Name: ArtAssist
510(k) number: K131146

Specific indications include:
When surgery is contraindicated
While waiting for surgery
Intermittent claudication
Rest pain
Diabetic foot
Ischemic neuritis
Arterial ulcers
Gangrene
Poor runoff

Prescription Use: YES
(Part 21 CFR 801 Subpart D)